REMARKS

1. General

Claims 1 – 10 are pending in the Application.

Claims 1 – 3, 5 – 6 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over Henley et al. (**Henley**) 6,458,109 in view of Hibner et al. (**Hibner**) 6,120,462 and further in view of Overton et al. (**Overton**) 5,611,846.

Claim 4 is rejected under 35 U.S.C. §103(a) as being unpatentable over Henley et al. (**Henley**) 6,458,109 in view of Hibner et al. (**Hibner**) 6,120,462 and further in view of Overton et al. (**Overton**) 5,611,846 and further in view of Lewis et al. (**Lewis**) 6,017,440.

Claim 7 is rejected under 35 U.S.C. §103(a) as being unpatentable over Henley et al. (**Henley**) 6,458,109 in view of Hibner et al. (**Hibner**) 6,120,462 and further in view of Overton et al. (**Overton**) 5,611,846 and further in view of Scherson et al. (**Scherson**) 5,855,570.

Claim 8 is rejected under 35 U.S.C. §103(a) as being unpatentable over Henley et al. (**Henley**) 6,458,109 in view of Hibner et al. (**Hibner**) 6,120,462 and further in view of Overton et al. (**Overton**) 5,611,846 and further in view of **Fleischmann** 6,398,767.

Claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Henley et al. (**Henley**) 6,458,109 in view of Hibner et al. (**Hibner**) 6,120,462 and further in view of Overton et al. (**Overton**) 5,611,846 and further in view of Parker et al. (**Parker**) 4,955,391.

2. Claims 1 - 3, 5 – 6 and 10

The Examiner has rejected Claims 1 – 3, 5 – 6 and 10 under 35 U.S.C. §103(a) as being unpatentable over Henley et al. (**Henley**) 6,458,109 in view of Hibner et al. (**Hibner**) 6,120,462 and further in view of Overton et al. (**Overton**) 5,611,846. Applicant will show herein that it would not have been obvious to one skilled in the art to have combined the cited references in the manner set forth by the Examiner.

A. The pressure sensors of Henley and Hibner are fundamentally different from the sensors of the present invention.

The Examiner has cited **Henley** and **Hibner** as teaching the use of a sensing device in conjunction with a negative pressure wound treatment system having components similar to

those components described and claimed in the present application. The Examiner combines the two references primarily in an effort to address the order of placement of the components in the system. The Applicant has previously shown and emphasized this order as being an important distinction, not only with regard to structure but also function. More fundamental, however, than the issues surrounding the positioning and placement of the sensor (which remains an important distinction) is the basic distinction between the pressure sensors of **Henley** and **Hibner** and the types of sensors contemplated and claimed in the present case.

It has long been known to monitor pressure in conjunction with negative pressure wound treatment systems. As the Examiner correctly states; "Pressure sensors are commonly known in the art for sensing if there is too little vacuum pressure or too much vacuum pressure." Pressure sensors, however, belong to a category of "static" sensors that directly measure a basic property of a substance and as such do not require the kind of "active interaction" with the substance that is required in the present case. A pressure sensor, similar in many respects to a temperature sensor, need only come into indirect contact with the substance in question (a gas in most cases or a liquid/gas combination in some instances) to obtain a measurement of this fundamental characteristic of all gases. Such measurements do not require that the material flow past the sensor or even that the material flow at all. In addition the pressure sensor requires but a single point of contact and does not generally introduce any "interrogating" signal into the material.

The sensors as claimed and described in the present application, on the other hand, are "active" interrogating sensors and seek to characterize a specific compositional characteristic of the material (the fluid), namely the presence and concentration of infectious agents and/or infectious agent indicators, within the fluid associated with the wound. This distinction is significant because one could not simply substitute the types of sensors described and claimed in the present application for the pressure sensors of **Henley** and **Hibner** and expect these "active" sensors to function. Certainly the optical based sensors of the present invention that direct an interrogating light wave into the fluid and then measure (by reflection or transmission) the frequency characteristics of the light, could not function by simple substitution with the pressure sensors of **Henley** and **Hibner.** Even the pH sensors mentioned as an alternative in the present specification could not simply be substituted for the pressure sensors of **Henley** and **Hibner** because pH measurements rely on a direct immersion into the fluid being measured.

The corollary of the above is also evident, namely that the pressure sensors of **Henley** and **Hibner** could not function with the fluid environment required by the sensors of the present invention. Significantly the pressure sensors of **Henley** and **Hibner** are limited to measurements associated with the pressure of a gas within a sealed volume. The sensors of the present invention, on the other hand, rely upon a flow of liquid through or across the sensor in order to detect changes in the composition of the fluid (not just its pressure, temperature or volume). More complex structures are therefore required within the system in order to effect the measurements desired. It is worth noting that in both **Henley** (at Fig. 19, components 172 and 174) and **Hibner** (at Fig. 14, component 328) the pressure sensor is simply a "tap" into a gas flow conduit and nowhere do these sensors contemplate measurements associated with the composition of a fluid, much less a fluid that flows through the sensor for this purpose. In other words, there would be a great deal of further modification to the systems of **Henley** and **Hibner** before one could simply substitute the compositional sensors of the present invention for the static gas property sensors of the cited references.

B. Overton does not teach the use of a "photo diode" but merely provides a gas chromatograph structure suitable for use in the present invention.

Overton provides no help to either **Henley** or **Hibner** to suggest the system of the present invention. **Overton** is cited within the present application as describing one type of sensor that might appropriately be integrated into the negative pressure wound care system. This could clearly not be accomplished, however, in the manner in which **Henley** and **Hibner** use routine pressure sensors to monitor the vacuum pressure within the system.

Overton shows a gas chromatograph that includes a photoionization detector (column 12, lines 23 – 26 and Fig. 4, component 212). This photoionization detector **does not**, however, contain a photo diode as the Examiner indicates. The present invention describes the use of a gas chromatograph of the type shown in **Overton** (because of its small size and minimal power requirements) **in conjunction with** the photo diodes as shown and described in the present case (see Paragraph [0024], lines 9 -11 of the present specification). The photo "effect" that occurs in **Overton** (in Fig. 4) is the ionization of the gas (by way of a UV light source) within the quartz chamber in a manner that **alters the conductivity across the gas** as measured by the electrical circuitry shown, which comprises two electrodes on either side of the gas. (See Overton, column

12, lines 23 – 28, which state; "The gases flow through transparent quartz connector **210**, where ultraviolet light source **222** sends light through the flowing gas, causing changes in conductivity that may be detected with photoionization detector 212. **(Note the electrical connections between detector 212, tubular heater 202, and tube 214.)**", [emphasis added]. The "photo effect" that occurs in the photoionization detector is a change in the conductivity **of the gas**, not a change in the conductivity of a diode positioned in the circuit. This electrical circuitry happens to include diodes, but **not photo diodes**. Photo diodes are solid state devices that respond to light that is directed at their semiconductor surfaces in a manner that changes a voltage across the diode. The accepted schematic symbol for photo diodes is the triangular diode symbol, surrounded with a circle with two short arrows representing light waves pointed towards the diode. The symbol used in **Overton** is not that of a photo diode but is simply a diode. In **Overton** the diodes shown in the schematic are simple current "blocking" diodes associated with the electrical potential established across the gas conduit.

Claim 3 has been amended to clarify the distinction discussed above. Gas chromatographs function primarily to separate the components of a gas mixture (or the components of a fluid mixture that has been flash heated to a gaseous state). After separation, various types of "tests" can be carried out to distinguish and identify the compositions. Some of these "tests" involve light waves which consideration leads to the usefulness of the photo diodes operable in conjunction with the gas chromatograph.

There is nothing, however, in **Overton** that would lead one skilled in the art to look back to **Henley** and **Hibner** for its usefulness in the present case. As mentioned above, it is merely the small size and low power requirements that make this "compositional sensor" appropriate in conjunction with the present invention. Once again, the pressure sensors of **Henley** and **Hibner** have nothing in common with the compositional analyzer (sensor) device of **Overton** or the present invention.

3. Claim 4

Claim 4 is rejected under 35 U.S.C. §103(a) as being unpatentable over Henley et al. **(Henley)** 6,458,109 in view of Hibner et al. **(Hibner)** 6,120,462 and in view of Overton et al. **(Overton)** 5,611,846 and further in view of Lewis et al. **(Lewis)** 6,017,440.

Claim 4 depends from Claim 1 which should be allowable for the reasons stated above which are repeated here. **Lewis** does not cure the lack of teaching provided by **Henley** and **Hibner** with respect to the types of "sensors" involved.

4. Claims 7 – 9

Claim 7 is rejected under 35 U.S.C. §103(a) as being unpatentable over Henley et al. **(Henley)** 6,458,109 in view of Hibner et al. **(Hibner)** 6,120,462 and further in view of Overton et al. **(Overton)** 5,611,846 and further in view of Scherson et al. **(Scherson)** 5,855,570. Claim 8 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Henley** in view of **Hibner** and in view of **Overton** and further in view of **Fleischmann** 6,398,767. Claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Henley** in view of **Hibner** and in view of **Overton** and further in view of Parker et al. **(Parker)** 4,955,391.

Claims 7, 8 and 9 each depend from Claim 6 which should be allowable for the reasons stated above which are repeated here. **Scherson, Fleischmann** and **Parker** (respectively) do not cure the lack of teaching provided by **Henley** and **Hibner** with respect to the types of sensors involved.

5. Summary and Conclusion

Applicant believes the amendments contained herein are fully supported by the original disclosure in this application as filed, and as amended distinguish the present invention from the prior art cited in the case. Applicant respectfully requests allowance of the remaining claims in the application as amended. Should any further impediments to allowance of the claims exist, Applicant requests that the Examiner contact the undersigned attorney by phone.

Petition for Extension pursuant to Section 1.136(a) in accordance with Section 1.17 is herewith made. The Commissioner is authorized to charge the 2 months extension fee in the amount of $450.00, the RCE filing fee in the amount of $790.00, and any additional fees that may be required, or credit any overpayment made with this Office Action, to Deposit Account Number 500326.

Respectfully submitted,

Robert W. Mason

For Applicant

Robert W. Mason
Reg. No. 42,848
Kinetic Concepts, Inc.
8023 Vantage Drive, Ste. 540
San Antonio, Texas 78230
Telephone 210.255.6271
Facsimile 210.255.6969
Email: masonrw@kci1.com

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